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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,906	02/23/2004	Hugo X. Gonzalez	SPIRTN.017C1	6137

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/784,906	Applicant(s) GONZALEZ, HUGO X.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/2/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 7/2/04 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

1. The disclosure is objected to because of the following informalities: the reference to the prior application(s) from which benefit of priority is claimed fails to include the status of the parent application(s). The following format is suggested: "This is a continuation (continuation-in-part or division) of Application No._____, filed _____, now (abandoned, pending or U.S. Patent No._____)". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6 - 8 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by US 3,889,657 to Baumgarten.

In regards to claims 1, 2, 6 - 8 and 10, Baumgarten discloses a device (Figure 2) including an elongate body (7) having a proximal end, a distal end, and a lumen therethrough; a head (1, 2, 4) disposed at the distal end of the elongate body and having a lumen therethrough in communication with the elongate body lumen (Col. 3, line 5); a collection bag (16) configured to be disposed in the elongate body, the collection bag having a distal end (18) open to receive a body tissue sample, and

Art Unit: 3736

further configured with vacuum apertures to allow a vacuum to be drawn through the bag; a source of vacuum in selective communication with the proximal end of the elongate body (Col. 2, lines 36 – 37); and wherein the head is configured to selectively allow the tissue sample to be drawn into the elongate body and into the collection bag in that the head can be selectively positioned and agitated by a practitioner (Col. 2, lines 62 – 67). The head is capable of engaging and maintaining the position of a sample before, during and after resection. The collection bag is disposed adjacent the head and the distal end of the bag is secured to the head (Col. 3, lines 6 – 22). The collection bag is formed of a biocompatible material (Col. 3, lines 47 – 50; lines 63 – 66). The lumen extending through the head has an adjustable diameter (Col. 4, lines 12 – 16) in that when the tube is bent the diameter is reduced. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); *In re Ludtke*, 441 F.2d 664, 169 USPQ 566 (CCPA 1971).

Art Unit: 3736

4. Claims 1 – 8 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by US 5,197,485 to Grooters.

In regards to claims 1 – 8 and 10, Grooters discloses a device (Figure 2) including an elongate body (24) having a proximal end, a distal end, and a lumen therethrough; a head (12, 14) disposed at the distal end of the elongate body and having a lumen therethrough in communication with the elongate body lumen; a biocompatible collection bag (26) configured to be disposed in the elongate body, the collection bag having a distal end (26b) open to receive a body tissue sample (Col. 4, lines 18 – 21), and further configured with vacuum apertures (Col. 4, lines 21 – 22) to allow a vacuum to be drawn through the bag; a source of vacuum in selective communication with the proximal end of the elongate body (Col. 4, lines 33 – 34); and wherein the head is configured to selectively allow the tissue sample to be drawn into the elongate body (Col. 4, lines 50 – 55). The head is capable of engaging and maintaining the position of a sample before, during and after resection. The head is configured with a separator (16) that separates the interior of the head from the interior of the elongate body to inhibit the tissue sample from being drawn into the elongate body. The separator provides a region of decreased diameter (16c) between the head and the interior of the elongate body (Col. 3, lines 61 – 63) and is selectively activated (Col. 3, line 67 – Col. 4, line 10; lines 50 – 52). The collection bag is disposed adjacent the head and the distal end of the bag is secured to the head (Col. 4, lines 21 – 25).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

Art Unit: 3736

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,889,657 to Baumgarten as applied to claim 8 above.

In regards to claim 9, Baumgarten discloses the collection bag being formed of a polymeric material (Col. 3, lines 47 – 50), but fails to disclose the bag being formed of silicone. However, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case it would have been obvious to one having ordinary skill in the art to form the bag as disclosed by Baumgarten with silicone because silicone is a polymer commonly used in medical devices and known for its suitability within medical devices.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

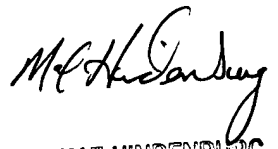
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



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